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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/369,016 08/05/99 FARMER S GANEDEN-04(1

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HM22/0906

EXAMINER

MARX, I

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

13

09/06/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/369,016

Applicant(s)

Farmer

Examiner

Irene Marx

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 27, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 51-60 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

The amendment filed 6/27/01 is acknowledged. Claims 51-60 are being considered on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-55 and 58-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for a "mineral" citrate or gluconate. As a matter of fact, it is unclear what this designation is intended to encompass.

Therefore, this material raises the issue of new matter and should be deleted.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-55 and 58-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51-55 and 58-59 are vague, indefinite and confusing in the recitation of "a mineral citrate" or "a mineral gluconate". It is unclear what this designation is intended to encompass even when interpreting the claims in light of the specification. See also the new matter rejection *supra*.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 51 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Paul '989. See, e.g., Formulation J, col. 15, lines 10-19, containing a lactic-acid producing bacterium, a fructo-oligosaccharide and sodium gluconate.

Claim 57 is rejected under 35 U.S.C. 102(e) as being anticipated by Reid '551. See, e.g., col. 7, lines 57-65 and col. 9, lines 35-45 for the administration to a mammal of a suppository comprising a lactic acid producing bacteria. The effect of increasing bioavailability of nutrients is an inherent property of the composition.

Claim 60 is rejected under 35 U.S.C. 102(e) as being anticipated by Langrehr in light of Long *et al.*. Langrehr discloses a composition comprising *B. coagulans* and fructo-oligosaccharides. Long *et al.* adequately demonstrates that the presence of lactase in *B. coagulans* is inherent in the species. See, e.g., Langrehr, col. 5, lines 15-25 and Long *et al.*, col. 4, lines 6-39.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hata taken with Paul and Hansen and further taken with Long.

Hata teach a process of providing a mammal with nutrients by orally administering yogurt containing *Bacillus coagulans*. The natural effect of consuming *Bacillus coagulans* containing compositions is to increase bioavailability of nutrients. The reference differs from the claimed invention in that the yogurt does not contain a fructo-oligosaccharide and gluconate or citrate.

However, Paul discloses compositions containing lactic acid bacteria and fructo-oligosaccharides, with the indication that fructo-oligosaccharides are a valuable addition to lactic acid bacterial compositions because of their contents of soluble fiber. In addition the reference teaches the combination of a lactic-acid producing bacterium, a fructo-oligosaccharide and sodium gluconate. (See, e.g., col. 15, lines 10-20). Moreover, Hansen *et al.* disclose the addition of various citrates and gluconates to yogurt, including calcium gluconate and/or calcium citrate for the purpose of adding valuable bioavailable nutrients (See, e.g., col. 4, lines 45) as well as the addition of fibers, which suggests the addition of fructo-oligosaccharides.

The references appear to differ from the claimed invention in that the compositions disclosed do not explicitly recite the presence of lactase. However, Long *et al.* adequately demonstrates that the presence of lactase in *B. coagulans* is inherent in the species. See, e.g., Long *et al.*, col. 4, lines 6-39. Accordingly, one of ordinary skill in the art would have been motivated to administer *B. coagulans* in milk-containing compositions, such as yogurt, with a reasonable expectation of providing compositions which are easily digestible in view of the availability of the lactose degrading enzyme lactase produced by this microorganism.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose as noted *supra*. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, highly dependent upon specific proportions and/or amounts of particular ingredients. Any

mixture of the components embraced by the claims which does not exhibit an unexpected result is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition and process of administering nutrients and disclosed by Hata by supplementing the milk-containing composition yogurt, for example, with citrate or gluconate compounds as taught by Paul and Hansen for the expected benefit of increasing the digestibility and the nutritional content of food and thus maximize the health benefits to the mammal being fed.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .

A handwritten signature in cursive script, appearing to read "Irene Marx".

Irene Marx  
Primary Examiner  
Art Unit 1651